



Billing Code: 4150-36-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of the Assistant Secretary for Health.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHP) will hold a meeting that will be open to the public. Information about SACHP and the full meeting agenda will be posted on the SACHP website at: <http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html>.

DATES: The meeting will be held on Wednesday, October 29, 2014, from 8:30 a.m. until 5:00 p.m. and Thursday, October 30, 2014, from 8:30 a.m. until 4:00 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FUTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHP; U.S. Department of Health and Human Services, 1101 Wootton

Parkway, Suite 200, Rockville, Maryland 20852; 240-453-8141; fax: 240-453-6909;
e-mail address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., Wednesday, October 29. Following opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, new members will be introduced. The Subpart A Subcommittee (SAS) will then give their report on the new SAS initiative examining informed consent. SAS is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment. SAS was established by SACHRP in October 2006. Following this report, an OHRP staff member will present and discuss OHRP data addressing incidental findings and corrective action plans.

On October 30, the Subcommittee on Harmonization (SOH) will discuss their work on the topic of the intersection of the HHS and FDA regulations and “big data”; this will be followed by a presentation of SOH work on the topic of return of general results. SOH was established by SACHRP at its July 2009 meeting. SOH is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the SACHRP at the address/phone number listed above at least one week prior to the meeting. Pre-registration is required for participation in the on-site public comment session; individuals may pre-register the day of the meeting. Individuals who would like to submit written statements should email or fax their comments to SACHRP at SACHRP@hhs.gov at least five business days prior to the meeting.

Dated: September 29, 2014.

Jerry Menikoff, M.D., J.D.,
Executive Secretary, Secretary's Advisory Committee on
Human Research Protections,
Director, Office for Human Research Protections.

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